CLIA CATEGORIZATIONS AND CLIA WAIVER

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CLIA CATEGORIZATIONS (1)

- **Most IVDs are CLIA categorized as either: waived, moderately complex, or highly complex.**
- **There are sub-categories for provider-performed microscopy (PPM) and some IVD systems are exempt from CLIA categorization due to lack of physical sample, e.g., pulse oximeters.**

CLIA CATEGORIZATIONS (2)

- **The CLIA category drives the CLIA requirements for the 5 CLIA Standards:**
  - **Quality assurance**
  - **Quality control**
  - **Personnel standards**
  - **Proficiency testing**
  - **Patient test management**

CLIA CATEGORIZATIONS (3)

- **The "delta" between waived and non-waived requirements is large, while the delta between moderate and highly complex is minimal.**
  - **Differences in: personnel standards, type of certification, and fees.**
  - **Each lab is regulated by its highest CLIA complexity test.**

CLIA CATEGORIZATIONS (4)

- **CLIA categorization for moderate or highly complex is based on the numerical score assigned to each test system.**
- **Waived tests are waived by: regulation, waiver petition, or home-use clearance (more discussion later)**

CLIA CATEGORIZATIONS (5)

- **Scores for moderate and highly complex tests are based on a 1 to 3 scale (increasing difficulty) for each of 7 parameters.**
- **Scores between 7 and 12 are assigned to "moderate," and scores at 13 and above are assigned to "highly complex."**
- **Levels of 1, 2, or 3 were assigned by CDC in 1992.**

CLIA CATEGORIZATIONS (6)

- **The 7 parameters:**
  - **Knowledge**
  - **Training and experience**
  - **Reagent and materials preparation**
  - **Characteristics of operational steps**
  - **Calibration, QC, and PT materials**
  - **Troubleshooting and maintenance**
  - **Interpretation and judgment**

CLIA CATEGORIZATIONS (7)

- **Therefore, the final score is totally objective, but the interim scoring (degree of difficulty- 1, 2, or 3) is subjective.**
- **CDC did not/does not publish the individual scores per parameters, but there are no 7's or 8's*; the simplest test systems have scores of 9. (* per personal conversation at CLIAC in 1992).**

CLIA WAIVER (1)

- **Test system becomes CLIA waived by:**
  - **Regulation,**
  - **FDA clearance for home-use**
  - **Waiver petition**

CLIA WAIVER (2)

- **Tests waived by regulation (1992):**
  - Dipstick/tablet urinalysis
  - Ovulation test (visual color)
  - Pregnancy test (color or direct result)
  - Sedimentation rate (non-automated)
  - Hemoglobin (copper sulfate)
  - Fecal occult blood
  - Spun hematocrit
  - HemoCue total hemoglobin (see next)

CLIA WAIVER (3)

- **HemoCue- "(added 1/19/93)** ***Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout."***
- **After HemoCue, decision made to not allow individual test systems to be waived by regulation- need CLIA waiver petition.**

CLIA WAIVER (4)

- **CLIA Waiver Route #2: FDA clearance for home use**
  - **The professional version is automatically CLIA waived for professional use- the OTC version is exempt from CLIA, as only lab-reported results are subject to CLIA.**
  - **The professional version of the test system includes different packaging and different labeling.**

CLIA WAIVER (5)

- **Waiver by Petition**
  - **Follow FDA's 2008 Guidance**
    - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070890.pdf
  - **Major Elements:**
    - **Test system characteristics**
    - **Clinical studies**
    - **Failure alerts and fail-safe mechanisms**
    - **Labeling requirements**

CLIA WAIVER (6)

- **Test System Characteristics:**
  - **Is a fully automated instrument, or a unitized, or self-contained test.**
  - **Uses direct unprocessed specimens such as capillary or venous whole blood.**
  - **Needs only basic, non-technique-dependent specimen manipulation.**
  - **Needs only basic, non-technique-dependent reagent manipulation.**

CLIA WAIVER (7)

- **Test System Characteristics: (con't)**
  - **Needs no operator intervention during the analysis steps.**
  - **Needs no technical or specialized training with respect to troubleshooting or interpretation of multiple, or complex error codes.**
  - **Needs no electronic or mechanical maintenance.**
  - **Produces results that require no operator calibration, interpretation, or calculations.**

CLIA WAIVER (8)

- **Test System Characteristics: (con't)**
  - **Produces results that are clear to read, such as 'positive or negative', a direct readout of numerical values, the clear presence or absence of a line, or obvious color gradations.**
  - **Provides instructions and materials for obtaining and shipping specimens for confirmation testing, in cases where such testing is clinically advisable.**

CLIA WAIVER (9)

- **Test System Characteristics: (con't)**
  - **Has test performance comparable to a traceable reference method, as demonstrated by studies in which intended operators perform the test.**
  - **Contains a quick reference instruction sheet that is written at no higher than a 7th grade reading level.**

CLIA WAIVER (10)

- **Clinical Studies for CLIA Waiver**
  - **3 sites (minimum)**
  - **120 subjects/site (minimum**
  - **Samples representative of dynamic range**
  - **Split testing with “pedigreed” comparative method**
  - **Minimum 9 operators in study (~3/site)**
  - **No training of operators**

CLIA WAIVER (11)

- **Clinical Studies for CLIA Waiver (con't)**
  - **Operators complete questionnaires**
  - **Collect operator demographics for age, education, experience, daily tasks**
  - **Data requirements are very stringent**
  - **Labeling considerations**
    - **7th grade reading level**
    - **Quick Reference Guide (plus insert)**

CLIA WAIVER (12)

- **Failure Alerts/Fail-Safe**
  - **Resistant to environmental factors**
  - **Identifiable sources of errors**
  - **Identifying errors vs locked out results**
  - **Recommend 2-tier approach**
    - **Risk analysis and flex studies**
    - **Failure alert and fail-safe validation**

QUESTIONS??